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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,000

02/17/2005

Roland Suck

MERCK-2975

2809

23599 7590 06/20/2007
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

ROONEY, NORA MAUREEN

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,000	Applicant(s) SUCK ET AL.	
	Examiner Nora M. Rooney	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> . |

DETAILED ACTION

1. Applicant is reminded that “use” claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)). For examination purposes “use” claims are interpreted as a method of the first recited “use”.

Election/Restrictions

2. Applicant's amendment filed on 02/17/2005 is acknowledged.
3. Restriction is required under 35 U.S.C. 121 and 372.
4. This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.
5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-6, 12-15, 17, drawn to a Phl p 1 allergen variant and pharmaceutical composition thereof.

Group II, Claims 7-11, 19 and 21, drawn to a DNA molecule encoding an allergen variant, a recombinant DNA expression vector and a process for the preparation of the allergen variant

Group III, Claim 16, drawn to a method of using a Phl p 1 allergen variant for preparation of a medicament for the treatment of allergies.

Group IV, Claim 18, drawn to a method of using a Phl p 1 allergen variant for in vitro diagnosis of allergies.

Group V, Claim 20, drawn to a method of using an expression vector containing a DNA molecule encoding a Phl p 1 variant for the preparation of a medicament for the treatment of allergies.

6. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of U.S. Patent 7,001,743.

U.S. Patent 7,001,743 teaches a variant of Phl p 1 from timothy grass characterized in that it has an addition Cys residue compared with the wild type between amino acid 94 and 95 of SEQ ID NO:2 (In particular, see SEQ ID NO:20 of '743 reference and attached sequence alignment). SEQ ID NO:20 of the '743 is a variant of Phl p 1 of SEQ ID NO:2 of the instant application having 40.7% sequence identity over amino acids 14-239 of SEQ ID NO:2 with 112 matches, 35 conservative substitutions, 69 mismatches and 21 inserted amino acids.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an

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election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

7. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C. 121: (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If any of Groups I, III or IV is elected, applicant is further required to elect:

a single specific Phl p 1 variant as recited in claims 1-6 having a specified sequence with specified additional Cys residue(s).

If either of Group II or V is elected, applicant is further required to elect:

a single specific DNA encoding a single specific Phl p 1 variant having a specified sequence with specified additional Cys residue(s) as recited in claims 1-6.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; and the immunoassays differ with respect to ingredients, method steps and endpoints; thus each condition and immunoassay represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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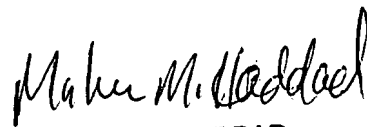
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 7, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600


MAHER M. HADDAD
PRIMARY EXAMINER

RESULT 42

US-10-125-001-20

; Sequence 20, Application US/10125001
 ; Patent No. 7001743
 ; GENERAL INFORMATION:
 ; APPLICANT: Cosgrove, Daniel J.
 ; APPLICANT: Wu, Yajun
 ; TITLE OF INVENTION: No. 7001743el Expansin Polynucleotides, Related
 Poly peptides and Methods of Use
 ; FILE REFERENCE: P05630US1
 ; CURRENT APPLICATION NUMBER: US/10/125,001
 ; CURRENT FILING DATE: 2002-04-18
 ; PRIOR APPLICATION NUMBER: 60/285,050
 ; PRIOR FILING DATE: 2001-04-19
 ; NUMBER OF SEQ ID NOS: 22
 ; SOFTWARE: PatentIn version 3.1
 ; SEQ ID NO 20
 ; LENGTH: 247
 ; TYPE: PRT
 ; ORGANISM: Oryza sativa
 US-10-125-001-20

Query Match 40.7%; Score 537.5; DB 3; Length 247;
 Best Local Similarity 47.3%; Pred. No. 5.8e-45;
 Matches 112; Conservative 35; Mismatches 69; Indels 21;
 Gaps 8;

Qy	14	YGGKWLDKSTWYGKPTAAGPKDNGGACGYKD-VDKPPFSGMTGCGNTPIFKSGRGCGSC	72
		: : : : :	
Db	17	YG--WSSGGATWYGGPQGDG--SEGGACGYQSAVGQRPFSMIAAGGPSLFGKNGKCGSC	72
Qy	73	FEIKCTKPEACSGEPVVHITDD-----NEEPIAAYHFDLSGIAFGSMAKKGDEQKLR	125
		:	
Db	73	YQIKCTGNRACSGRPVTVVITDSCPGGVCLNE---AAHFDMSGTAFGAMANRGMGDLRL	128
Qy	126	SAGEVEIQFRRVKCKYPEGTKVTFHVEKGSNPNYLALLVKFVAGDGDVVAVDI-KEKGKD	184
		: :	
Db	129	SAGVLKIYKRVPCRF--AMNVAFKVDAGSNPYLAILVQYANGDGDLAHVHIMKARGGG	186
Qy	185	KWIALKESWGAIWRI--DTPEVLKGPFTVRYTTEGGTKGEAKDVIPEGWKADTCYES	239
		: : : : . : : :	
Db	187	GWKAMQQSWGATWRLNSNTGKPLSPFISIRLTSGSGKVLVANNVIPSGWQAGLTYRS	243